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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,932	09/09/2003	David N. Ku	9537-3	3113
20792	7590	04/13/2009	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				WILLSE, DAVID H
ART UNIT		PAPER NUMBER		
3738				
MAIL DATE		DELIVERY MODE		
04/13/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/658,932	KU, DAVID N.	
	<b>Examiner</b>	<b>Art Unit</b>	
	David H. Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 December 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11, 14-25, 28, 29, 34-45 and 47-74 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10, 11, 53-55 and 70 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7, 9, 14-25, 28, 29, 34-45, 47-52, 56-69 and 71-74 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1-27-09</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9, 14-25, 28, 29, 34-45, 47-52, 56-69, and 71-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruberti et al., US 2004/0092653 A1, which discloses a spinal intervertebral disc (paragraph **0027**; etc.) being a single non-articulation body of a single solid biocompatible elastomer of PVA cryogel cross-linked by freeze-thaw processing (paragraph **0078**; etc.). The single body defines an exposed surface that is modified to provide specific surface characteristics (paragraph **0030**; etc.). The language added to instant claim 1 and others constitutes a product-by-process limitation and does not appear to distinguish the *product* of the claimed invention over the preferred embodiment of Ruberti et al., because freeze-thaw processing alone and the combined processing steps favored by Ruberti et al. all result in “physical” crosslinking, as described in paragraphs **0086** and **0104**, for example (MPEP § 2113). Moreover, that Ruberti et al. teach an advantageous PVA hydrogel which is both a thetagel and a cryogel (e.g., paragraph **0014**) does not imply that cryogels alone are unobvious from the Ruberti

et al. disclosure. In fact, Ruberti et al. are clearly open to PVA hydrogels being formed by freeze-thaw processing only, because nanostructuring, for instance, is not limited to thetagels (paragraph **0134**) and because freeze-thaw cycling alone is compatible with incorporated molecules that can tolerate such cycles (paragraph **0085**, which, like the Applicant's specification, incorporates US 6,231,605 B1 by reference). Therefore, the physical cross-linking only by freeze-thaw processing would have been an inherent variation, even though such was not the most preferred method, and would also have been obvious in order to simplify manufacturing of the prosthesis.

Ruberti et al. teach that “[t]he nucleus pulposus is always in compression, while the annulusfibrosis is always in tension” (paragraph **0003**) in the natural intervertebral disk, and that “the one-piece prosthetic intervertebral disk approximates the spatial distribution of the mechanical properties of the combination of the nucleus pulposus and the annulus fibrosis of the natural intervertebral disk” (paragraphs **0027**; **0034**; **0063**; **0077**; **0087**; etc.). Because “[t]he loads that any vertebral implant must withstand will be reasonably high (on the order of 4MPa in compression)”, and the compressive load is transferred “to a tensile circumferential load in the annulus fibrosis” (paragraph **0077**), an ultimate strength in tension greater than about 100 kPa would have been immediately obvious, if not inherent, to the ordinary practitioner. Likewise, since rotations of  $\pm 5^\circ$  are achieved in a natural disk (paragraph **0007**), the prosthesis having adequate viscoelastic properties (paragraph **0011**; etc.) to permit  $10^\circ$  of overall rotation would likewise have been obvious, if not inherent. Regarding claim 4 and others: paragraphs **0067**; **0075**; etc. Regarding claim 15 and others, the use of fabric, mesh, or the like to anchor a disk implant to adjacent vertebrae via screws and bone ingrowth (into the fabric or mesh) was well

known in the art at the time of the present invention and would have been obvious in order to stabilize the device relative to the spine.

**Response to Applicant's Remarks**

The Applicant appears to suggest that Ruberti et al. teach away from physical crosslinking (Applicant's reply of December 3, 2008: paragraph bridging pages 13 and 14; page 14, first and second paragraphs; etc.). The examiner disagrees: the Ruberti et al. disclosure teaches away from chemical crosslinking (e.g., paragraphs **0069** and **0072**) and instead favors an improved method (e.g., paragraph **0073**) involving *physical* crosslinking (paragraphs **0013**, **0038**, **0083**, **0104**, **0141**, etc.). The Applicant argues that claims 5, 40, and 74 are independently patentable over the cited art (Applicant's reply of December 3, 2008: page 15, first paragraph), but even Ruberti et al. embodiments characterized by anisotropic mechanical properties have smooth gradients (paragraphs **0075** and **0117**) and thus do not possess a distinct boundary between a core region and an annulus region.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday, Tuesday, and Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**/David H. Willse/  
Primary Examiner  
Art Unit 3738**